

EXHIBIT A

Jerry G. Blaivas, M.D.

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF
3 WEST VIRGINIA AT CHARLESTON

- - -

4 IN RE: ETHICON, INC., :Master File No.
5 PELVIC REPAIR SYSTEM :2:12-MD-0237
6 PRODUCTS LIABILITY :
7 LITIGATION :MDL No. 2327

8 -----
9 THIS DOCUMENT RELATES TO :JOSEPH R. GOODWIN
10 THE CASES LISTED BELOW :U.S. DISTRICT JUDGE
11 -----

12 Mullins, et al. V. Ethicon, Inc., et al.
13 2:12-cv-02952
14 Sprout, et al. V. Ethicon, Inc., et al.
15 2:12-cv-07924
16 Iquinto v. Ethicon, Inc., et al.
17 2:12-cv-09765
18 Daniel, et al. V. Ethicon, Inc., et al.
19 2:13-cv-02565
20 Dillon, et al. V. Ethicon, Inc., et al.
21 2:13-cv-02919
22 Webb, et al. V. Ethicon, Inc., et al.
23 2:13-cv-04517
24 Martinez v. Ethicon, Inc., et al.
25 2:13-cv-04730
26 McIntyre, et al. V. Ethicon, Inc., et al.
27 2:13-cv-07283
28 Oxley v. Ethicon, Inc., et al. 2:13-cv-10150
29 Atkins, et al. V. Ethicon, Inc., et al.
30 2:13-cv-11022
31 Garcia v. Ethicon, Inc., et al. 2:13-cv-14355
32 Lowe v. Ethicon, Inc., et al. 2:13-cv-14718
33 Dameron, et al. V. Ethicon, Inc., et al.
34 2:13-cv-14799

35 SEPTEMBER 17, 2015
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1 CAPTION CONTINUED:
2
3 Vanbuskirk, et al. V. Ethicon, Inc., et al.
 2:13-cv-16183
4 Mullens, et al. V. Ethicon, Inc., et al.
 2:13-cv-16564
5 Shears, et al. V. Ethicon, Inc., et al.
 2:13-cv-17012
6 Javins, et al. V. Ethicon, Inc., et al.
 2:13-cv-18479
7 Barr, et al. V. Ethicon, Inc., et al.
 2:13-cv-22606
8 Lambert v. Ethicon, Inc., et al.
 2:13-cv-24393
9 Cook v. Ethicon, Inc., et al. 2:13-cv-29260
 Stevens v. Ethicon, Inc., et al.
10 2:13-cv-29918
 Harmon v. Ethicon, Inc., et al. 2:13-cv-31818
11 Snodgrass v. Ethicon, Inc., et al.
 2:13-cv-31881
12 Miller v. Ethicon, Inc., et al. 2:13-cv-32627
 Matney, et al. V. Ethicon, Inc., et al.
13 2:14-cv-09195
 Jones, et al. V. Ethicon, Inc., et al.
14 2:14-cv-09517
 Humbert v. Ethicon, Inc., et al.
15 2:14-cv-10640
 Gillum, et al. V. Ethicon, Inc., et al.
16 2:14-cv-12756
 Whisner, et al. V. Ethicon, Inc., et al.
17 2:14-cv-13023
 Tomblin v. Ethicon, Inc., et al.
18 2:14-cv-14664
 Schepleng v. Ethicon, Inc., et al.
19 2:14-cv-16061
 Tyler, et al. V. Ethicon, Inc., et al.
20 2:14-cv-19110
 Kelly, et al. V. Ethicon, Inc., et al.
21 2:14-cv-22079
 Lundell v. Ethicon, Inc., et al.
22 2:14-cv-24911
 Cheshire, et al. V. Ethicon, Inc., et al.
23 2:14-cv-24
24

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<p style="text-align: right;">Page 106</p> <p>1 Q. And when you mention current 2 studies on the autologous fascial sling, 3 what current studies are you referring 4 to?</p> <p>5 A. I mean, there was just a 6 study by -- I don't remember who the 7 primary author was, the first author was. 8 But there was a study by Roger 9 Dmochowski's group. There's a study by 10 Eric Rovner comparing synthetic slings 11 to -- synthetic slings to autologous 12 fascia slings.</p> <p>13 And my recollection is that 14 the findings were comparable. But I 15 would really -- I would need to see those 16 papers to answer your question. I mean, 17 to answer with certainty.</p> <p>18 Q. You didn't cite to Dr. 19 Dmochowski's paper or Eric Rovner's paper 20 in your expert report, correct?</p> <p>21 A. No.</p> <p>22 Q. I'm not correct?</p> <p>23 A. Correct, yes.</p> <p>24 Q. Oh, thank you.</p>	<p style="text-align: right;">Page 108</p> <p>1 years, studies --</p> <p>2 A. Yes.</p> <p>3 Q. -- of midurethral slings 4 effectiveness.</p> <p>5 Do you see that?</p> <p>6 A. Yes, I do.</p> <p>7 Q. So there are 11 studies 8 mentioned here in Table 1, correct?</p> <p>9 A. Correct.</p> <p>10 Q. Were there more than 11 11 studies found that fulfilled these 12 criteria of a follow-up duration of five 13 years or more but for some reason did not 14 make it into Table 1?</p> <p>15 MS. FITZPATRICK: Objection.</p> <p>16 THE WITNESS: I honestly 17 don't know. I don't think so, but 18 I don't know for sure. I could 19 find out.</p> <p>20 BY MR. SNELL:</p> <p>21 Q. The sixth paper down is a 22 paper by Serati, 2013.</p> <p>23 A. Yes.</p> <p>24 Q. It looks like that involved</p>
<p style="text-align: right;">Page 107</p> <p>1 A. I thought you said you 2 didn't. Oh, okay.</p> <p>3 Q. Let's just -- we have a 4 double negative and that's my bad.</p> <p>5 How about we make it this 6 way: Did you cite to either Dr. 7 Dmochowski's paper or Dr. Rovner's paper 8 in your expert report?</p> <p>9 A. I did not.</p> <p>10 Q. Thank you.</p> <p>11 MR. SNELL: Let's take a 12 break.</p> <p>13 - - -</p> <p>14 (Whereupon, a brief recess 15 was taken.)</p> <p>16 - - -</p> <p>17 BY MR. SNELL:</p> <p>18 Q. In your paper that was 19 published this year on midurethral 20 slings, we were discussing the long-term 21 studies that were found, correct?</p> <p>22 A. Yes.</p> <p>23 Q. Table 1 says, Long-term 24 follow-up duration of more than five</p>	<p style="text-align: right;">Page 109</p> <p>1 transobturator slings.</p> <p>2 Do you see that?</p> <p>3 A. Correct.</p> <p>4 Q. And that had a duration of 5 follow up of 60 months?</p> <p>6 A. Yes.</p> <p>7 Q. Were you aware that there's 8 a paper by Serati on the TVT retropubic 9 device with a follow up of greater than 10 ten years using very similar methodology 11 to this paper that you cite regarding 12 transobturator slings?</p> <p>13 MS. FITZPATRICK: Objection 14 to form.</p> <p>15 THE WITNESS: No.</p> <p>16 BY MR. SNELL:</p> <p>17 Q. That's a paper you've never 18 read?</p> <p>19 MS. FITZPATRICK: Objection 20 to form.</p> <p>21 Can you identify the paper 22 specifically for him?</p> <p>23 MR. SNELL: Yes.</p> <p>24 BY MR. SNELL:</p>

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<p style="text-align: right;">Page 110</p> <p>1 Q. The ten-year plus Serati 2 paper on the TVT retropubic device, is 3 that a study you've read? 4 A. No. 5 MS. FITZPATRICK: Do you 6 have a copy of it? Or a cite to 7 it or something like that so we 8 have a clear record of what we're 9 talking about? 10 MR. SNELL: I'm sure we can 11 get a cite. 12 THE WITNESS: Or the year it 13 was published? 14 MS. FITZPATRICK: Or a copy 15 of the paper, too. 16 MR. SNELL: I'm not going to 17 ask him about something he hasn't 18 read, so -- 19 MS. FITZPATRICK: I just 20 want to make sure that you're both 21 talking about the same thing. So 22 he needs to see what the paper is 23 and say, yes, I've read it or no, 24 I haven't.</p>	<p style="text-align: right;">Page 112</p> <p>1 BY MR. SNELL: 2 Q. Doctor, I don't have a 3 printout, but I'll show it to you. 4 Tension-free Vaginal Tape for the 5 Treatment of Urodynamic Dynamic Stress 6 Incontinence: Efficacy and Adverse 7 Effects at 10-Year Follow Up, published 8 in the European Urology Journal, Volume 9 61, 2012. 10 Have you read that study? 11 A. Can I see it? 12 MS. FITZPATRICK: Can we get 13 a printout of that? 14 MR. ROSENBLATT: Yes. 15 MS. FITZPATRICK: That would 16 be great. Thanks. 17 BY MR. SNELL: 18 Q. Can I come look over your 19 shoulder, because I don't have a copy 20 either? 21 A. Sure. 22 Do you know why it's doing 23 that? 24 Q. I think the connection is</p>
<p style="text-align: right;">Page 111</p> <p>1 THE WITNESS: Can you repeat 2 that? 3 MS. FITZPATRICK: I said I 4 want him to show you the article 5 so you can say yes, I've read it 6 or no, I haven't, instead of just 7 asking. 8 BY MR. SNELL: 9 Q. In Table 1, there is no 10 ten-year TVT study, we can agree on that, 11 correct, by Serati, at all? 12 A. Correct. 13 Q. And you don't know whether 14 whoever did the searches came across it 15 and purposely did not put it in there for 16 some reason or another? 17 MS. FITZPATRICK: Objection. 18 THE WITNESS: It is -- I 19 would think that's highly, highly 20 unlikely that they came across it 21 and didn't include it. 22 I mean, I don't know, it 23 might have not met our search 24 criteria. I don't know.</p>	<p style="text-align: right;">Page 113</p> <p>1 very slow. 2 A. Oh, you're getting this off 3 the -- 4 Q. Yes. It's off the Internet. 5 A. This is what I want to see. 6 No, I don't remember seeing 7 that. And I want to just check one thing 8 here. 9 MR. SNELL: Do you have a 10 copy of this paper, Paul? 11 MR. ROSENBLATT: No. I can 12 get one made. 13 MR. SNELL: We'll come back 14 to that, Doctor. 15 THE WITNESS: Okay. 16 BY MR. SNELL: 17 Q. As far as you recall, you 18 don't remember reading that ten-year 19 paper by Serati at all? 20 A. No. Which doesn't mean I 21 haven't seen it. And I may have it -- I 22 may have seen it. 23 Q. If you'd go to Page 4. 24 A. May I just take one second?</p>

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<p style="text-align: right;">Page 114</p> <p>1 Q. Let's go off the record, 2 then. 3 - - - 4 (Whereupon, a discussion off 5 the record occurred.) 6 - - - 7 THE WITNESS: In the Nature 8 review article, we originally 9 included the methodology by which 10 we selected and rejected papers 11 and in the -- sorry. 12 I just -- we can go off the 13 record now. They moved it. 14 What I was going to say is 15 that -- 16 MS. FITZPATRICK: This 17 should be on the record. 18 THE WITNESS: I was looking 19 for the search criteria, and the 20 editors took it out of the method 21 section. And I just realized they 22 put it in a box on the side. So 23 I'd like to refresh my memory and 24 look at it.</p>	<p style="text-align: right;">Page 116</p> <p>1 done and they used terms, TVT 2 tension-free vaginal tape, tension free 3 vaginal sling. 4 Correct? 5 A. Correct. 6 Q. And the search was done, 7 limited to human patients, clinical data, 8 correct? 9 A. Correct. 10 Q. And this review was done in 11 August 2014? 12 A. Correct. 13 Q. And we just looked at the 14 Serati ten-year TVT study, and in the 15 title, it talks about tension-free 16 vaginal tape, correct? 17 A. Correct. 18 Q. And it was published in a 19 well-respected European urology journal 20 in 2012. 21 We saw that, right? 22 A. Correct. 23 Q. And it was in human women 24 with ten years or more duration of</p>
<p style="text-align: right;">Page 115</p> <p>1 BY MR. SNELL: 2 Q. You're looking at the last 3 page of -- 4 A. Page 21. 5 Q. Correct. 6 The last page of the paper, 7 before the references? 8 A. Yes. 9 Q. Under the color box that 10 says, Review criteria? 11 A. Yes. 12 We're on the record? 13 Q. Yes. We're on the record. 14 A. Unfortunately, they edited, 15 because of their journal guidelines, to 16 the point where I can't find the 17 information that I need to see whether or 18 not I would have seen that article or 19 rejected it or not. 20 So I will not have an 21 independent recollection of whether I saw 22 it or not. 23 Q. Just so we can agree, 24 though, it says, This says a search was</p>	<p style="text-align: right;">Page 117</p> <p>1 follow-up, correct? 2 A. Well, I haven't seen -- I 3 saw the title. I didn't read the -- look 4 at the paper. But in the title it says 5 ten years, yes. 6 MS. FITZPATRICK: If you're 7 going to ask him questions about 8 the article specifically, can we 9 get a copy? 10 MR. SNELL: I'm going to get 11 a copy. 12 BY MR. SNELL: 13 Q. But as you sit here, you 14 have no idea, then, why that paper did 15 not make it into the table that you 16 reported in your article of long-term 17 five-year studies? 18 A. That's correct. 19 Q. And there very well could be 20 other studies of five-years duration, or 21 more, with the TVT that, for reasons 22 unbeknownst to you, do not show up in 23 that table, correct? 24 MS. FITZPATRICK: Objection.</p>

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<p style="text-align: right;">Page 190</p> <p>1 Q. Yes.</p> <p>2 A. Yes, this was Burch. I'm</p> <p>3 quite certain about that, because I was</p> <p>4 shocked to see it. But it was so long</p> <p>5 ago that I read it, I couldn't possibly</p> <p>6 tell you when.</p> <p>7 Q. Considering that you</p> <p>8 included the five-year TVT-O study by</p> <p>9 Serati in that table but you didn't</p> <p>10 include this ten-year TVT study, as you</p> <p>11 sit here now, I know I asked you this</p> <p>12 earlier, but do you know why that was not</p> <p>13 captured?</p> <p>14 MS. FITZPATRICK: Objection.</p> <p>15 Asked and answered.</p> <p>16 THE WITNESS: I am going to</p> <p>17 find out. I don't know why.</p> <p>18 BY MR. SNELL:</p> <p>19 Q. This study is consistent</p> <p>20 with your review, in particular with</p> <p>21 regard to the rate of dyspareunia</p> <p>22 long-term with TVT, correct?</p> <p>23 MS. FITZPATRICK: Objection.</p> <p>24 THE WITNESS: A dyspareunia</p>	<p style="text-align: right;">Page 192</p> <p>1 A. Yes.</p> <p>2 - - -</p> <p>3 (Whereupon, Exhibit</p> <p>4 Blaivas-13, Heinonen Paper, was</p> <p>5 marked for identification.)</p> <p>6 - - -</p> <p>7 BY MR. SNELL:</p> <p>8 Q. I have another one for you.</p> <p>9 I'm not going to go through all of the</p> <p>10 ones, but I'm going to give you a couple</p> <p>11 of them.</p> <p>12 I've handed you Exhibit 13.</p> <p>13 This is a paper by Heinonen. This is a</p> <p>14 10.5 year follow-up with Ethicon TVT.</p> <p>15 Do you see that?</p> <p>16 A. Let me just take a look.</p> <p>17 Q. Sure. And I think we can be</p> <p>18 pretty brief about this one.</p> <p>19 This is a long-term study on</p> <p>20 TVT, correct, Doctor?</p> <p>21 A. Yes.</p> <p>22 Q. This paper was not</p> <p>23 identified in that long-term study table</p> <p>24 either in your review, correct?</p>
<p style="text-align: right;">Page 191</p> <p>1 rate of zero? No. It's not -- we</p> <p>2 don't have -- not a zero</p> <p>3 dyspareunia rate. It's no</p> <p>4 dyspareunia.</p> <p>5 BY MR. SNELL:</p> <p>6 Q. Right. Maybe I messed the</p> <p>7 question up.</p> <p>8 Actually, this study by</p> <p>9 Serati, the ten-year follow-up, is</p> <p>10 actually consistent with what you wrote</p> <p>11 in the AUA stress incontinence</p> <p>12 guidelines, correct, with regard to</p> <p>13 dyspareunia rates?</p> <p>14 A. That's correct, yes. I</p> <p>15 thought you were referring to our Nature</p> <p>16 article.</p> <p>17 Q. And this study by Serati,</p> <p>18 that you didn't include in the Nature</p> <p>19 article, is inconsistent with what you</p> <p>20 wrote in your review article, correct?</p> <p>21 A. In what way?</p> <p>22 Q. Because it reports zero</p> <p>23 dyspareunia and you say there's more,</p> <p>24 correct?</p>	<p style="text-align: right;">Page 193</p> <p>1 A. That's correct.</p> <p>2 Q. In this study, there was</p> <p>3 about 28 percent loss to follow up,</p> <p>4 correct? 138 of 191 patients were able</p> <p>5 to be evaluated?</p> <p>6 A. If you did the math, that</p> <p>7 looks about right. Okay.</p> <p>8 Q. They say 72 percent.</p> <p>9 Do you see that?</p> <p>10 A. I do.</p> <p>11 Q. So that's within that range</p> <p>12 of what's to be expected at ten years,</p> <p>13 correct?</p> <p>14 A. Yes.</p> <p>15 Q. And these authors concluded</p> <p>16 that the TVT was effective and safe even</p> <p>17 after ten years, correct?</p> <p>18 A. Yes. We've agreed that it's</p> <p>19 effective.</p> <p>20 The safe, just give me a</p> <p>21 moment, I'm checking.</p> <p>22 Okay.</p> <p>23 Q. Do you know why you didn't</p> <p>24 cite to this paper either in your table</p>

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<p style="text-align: right;">Page 194</p> <p>1 of long-term TVT studies?</p> <p>2 A. I do not.</p> <p>3 Q. They reported three --</p> <p>4 strike that.</p> <p>5 They reported three</p> <p>6 patients, 2.3 percent, had late-onset</p> <p>7 adverse events, correct?</p> <p>8 A. Where is that, please?</p> <p>9 Q. It's in the very front.</p> <p>10 A. Okay. I mean, I was looking</p> <p>11 in the methods, and there's nothing in</p> <p>12 the methods that I can see about</p> <p>13 adverse -- about any mechanism to</p> <p>14 follow-up for adverse events. So let me</p> <p>15 just --</p> <p>16 Q. Well, you see, if you look</p> <p>17 under the methods, the fourth paragraph</p> <p>18 above, when they brought these women back</p> <p>19 in for this 10.5 year follow-up visit --</p> <p>20 A. Where are you now?</p> <p>21 Q. Right here. Right above</p> <p>22 results. They did a gynecologic exam, a</p> <p>23 stress test, they reviewed the hospital</p> <p>24 records.</p>	<p style="text-align: right;">Page 196</p> <p>1 questionnaires -- I know most of these</p> <p>2 questionnaires, most of these</p> <p>3 questionnaires would ask specifically</p> <p>4 about dyspareunia or pelvic pain.</p> <p>5 Q. Did you see that they did</p> <p>6 gynecologic exams?</p> <p>7 A. Yes, but that's not --</p> <p>8 that's not a measure of pain.</p> <p>9 Q. Well, during -- you do</p> <p>10 gynecologic exams, correct?</p> <p>11 A. Yes.</p> <p>12 Q. And you know that when you</p> <p>13 do a gynecologic exam, you can elicit a</p> <p>14 painful response from the patient,</p> <p>15 correct?</p> <p>16 MS. FITZPATRICK: Objection.</p> <p>17 THE WITNESS: Yes.</p> <p>18 BY MR. SNELL:</p> <p>19 Q. Do these authors, at 10.5</p> <p>20 years, report that they elicited any type</p> <p>21 of painful response from any patient</p> <p>22 during their gynecologic exam?</p> <p>23 A. I don't see any methodology</p> <p>24 that would ask for that. I mean, the way</p>
<p style="text-align: right;">Page 195</p> <p>1 And it says, This was done</p> <p>2 to acquire information on later</p> <p>3 acquired...adverse events after the TVT</p> <p>4 operation.</p> <p>5 Correct?</p> <p>6 A. Yes, that would account for</p> <p>7 some complications. It would not account</p> <p>8 for the most impactful complication,</p> <p>9 which is chronic pain. You wouldn't,</p> <p>10 likely, go to the hospital for that.</p> <p>11 But I accept the rest of it.</p> <p>12 Q. Well, none of these patients</p> <p>13 reported chronic pain when they were</p> <p>14 assessed at 10.5 years, did they?</p> <p>15 A. I didn't see -- I looked,</p> <p>16 and I'll look again, but I don't see</p> <p>17 anything in the methodology where they</p> <p>18 were asked about that.</p> <p>19 General quality of life and</p> <p>20 the stuff that -- this was all -- so far</p> <p>21 as I can see, was -- all of these were</p> <p>22 questionnaires. I don't see anything</p> <p>23 that wasn't a questionnaire.</p> <p>24 And there are no</p>	<p style="text-align: right;">Page 197</p> <p>1 all these studies are done, eventually</p> <p>2 this stuff becomes a table, and the table</p> <p>3 is going to be a score and there's going</p> <p>4 to be a score for each of the symptoms.</p> <p>5 And unless there's a score for pain or a</p> <p>6 score for dyspareunia, even if the</p> <p>7 patient had it and even if they told</p> <p>8 someone, there isn't a mechanism that I</p> <p>9 can see in the methods to discover that.</p> <p>10 Q. So the different</p> <p>11 questionnaires, it's your statement that</p> <p>12 none of those questionnaires would have</p> <p>13 assessed pain or the impact of</p> <p>14 incontinence on sexual function?</p> <p>15 A. Even if -- I mean --</p> <p>16 Q. It's a yes-or-no question.</p> <p>17 A. What's that?</p> <p>18 MS. FITZPATRICK: Objection.</p> <p>19 Objection. You can answer it any</p> <p>20 way you need to, to fully,</p> <p>21 completely and truthfully answer</p> <p>22 the question.</p> <p>23 THE WITNESS: Please</p> <p>24 rephrase the question. Not</p>

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<p>1 rephrase, just restate it.</p> <p>2 BY MR. SNELL:</p> <p>3 Q. Do any of the questionnaires</p> <p>4 that they used assess sexual function in</p> <p>5 any manner?</p> <p>6 MS. FITZPATRICK: Objection.</p> <p>7 THE WITNESS: None of the</p> <p>8 ones that I recognize do. I mean,</p> <p>9 it's -- none of the ones that I</p> <p>10 recognize do, is the answer to the</p> <p>11 question.</p> <p>12 BY MR. SNELL:</p> <p>13 Q. This paper was published in</p> <p>14 the International Journal of Urology.</p> <p>15 Are you familiar with that</p> <p>16 journal?</p> <p>17 A. Yeah. Yes, I am.</p> <p>18 Q. Is that a good journal?</p> <p>19 MS. FITZPATRICK: Objection.</p> <p>20 THE WITNESS: I think</p> <p>21 it's -- yeah, I think it's an</p> <p>22 adequate journal.</p> <p>23 BY MR. SNELL:</p> <p>24 Q. Is this a good study or a</p>	<p>1 consequence of complications.</p> <p>2 That was the purpose of --</p> <p>3 that was the purpose of the</p> <p>4 review.</p> <p>5 - - -</p> <p>6 (Whereupon, Exhibit</p> <p>7 Blaivas-14, 2014 Laurikainen</p> <p>8 Article, European Association of</p> <p>9 Urology, was marked for</p> <p>10 identification.)</p> <p>11 - - -</p> <p>12 BY MR. SNELL:</p> <p>13 Q. Doctor, I'm handing you a</p> <p>14 five-year randomized control trial by</p> <p>15 Laurikainen, published in the European</p> <p>16 Association of Urology, January 2014.</p> <p>17 Do you see that?</p> <p>18 A. I do.</p> <p>19 Q. This is another study that</p> <p>20 didn't show up in that table in your</p> <p>21 review article, correct?</p> <p>22 A. Yeah, my -- I'm pretty sure</p> <p>23 that this one is after our -- even though</p> <p>24 it says 2014, I'm pretty sure this was</p>
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<p>1 poor study? How would you characterize</p> <p>2 this study that wasn't included in the</p> <p>3 table of your review?</p> <p>4 A. I would characterize this as</p> <p>5 a very good study. Both of these are</p> <p>6 very good studies.</p> <p>7 Q. Do you have any idea why</p> <p>8 this wasn't included?</p> <p>9 A. I do not.</p> <p>10 Q. Are you going to attempt to</p> <p>11 try to figure out why these ten-plus year</p> <p>12 TVT studies were left out of the table</p> <p>13 and which other ones may have been left</p> <p>14 out, too?</p> <p>15 MS. FITZPATRICK: Objection.</p> <p>16 THE WITNESS: I've already</p> <p>17 started doing that.</p> <p>18 But, in context, this review</p> <p>19 is not about efficacy, it's about</p> <p>20 complications. So there</p> <p>21 wouldn't -- this -- neither of</p> <p>22 these papers, as far as I'm</p> <p>23 concerned, adds very much to our</p> <p>24 understanding of the incidence and</p>	<p>1 after our review dates.</p> <p>2 And this one I have seen,</p> <p>3 though. This one, I do remember seeing</p> <p>4 this one before.</p> <p>5 Q. It's interesting that you</p> <p>6 say that, because, Doctor, earlier we</p> <p>7 looked at the review criteria, and it</p> <p>8 states that the systematic review was</p> <p>9 done in August 2014, which is, you know,</p> <p>10 eight months after this was published,</p> <p>11 correct?</p> <p>12 A. I was looking, I don't see</p> <p>13 the actual publication.</p> <p>14 Q. It says on the left,</p> <p>15 Published online, January 30, 2014.</p> <p>16 A. Then I don't have an</p> <p>17 explanation. I don't know what the exact</p> <p>18 date of our cutoff was.</p> <p>19 Q. But the search was done,</p> <p>20 actually, in August 2014, which is months</p> <p>21 after this was published?</p> <p>22 A. Okay.</p> <p>23 Q. We can agree to that,</p> <p>24 correct?</p>

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<p>1 need another one, correct?</p> <p>2 A. No. That's what I was</p> <p>3 saying before. I mean, we've seen many</p> <p>4 patients that have had -- had an</p> <p>5 intervention and are okay for a couple of</p> <p>6 years and then need another one.</p> <p>7 I mean, that's my practice.</p> <p>8 And I see that commonly.</p> <p>9 Q. I understand. I understand</p> <p>10 that that can occur.</p> <p>11 But I'm talking about</p> <p>12 probability.</p> <p>13 A. We specifically looked --</p> <p>14 was that a question? You did not ask a</p> <p>15 question yet, I'm sorry.</p> <p>16 Q. My question was focused on</p> <p>17 probability.</p> <p>18 I will give you that</p> <p>19 patients can go back for a second</p> <p>20 reoperation. I'm talking about</p> <p>21 probability and what the actual data</p> <p>22 showed.</p> <p>23 In this study -- let me see,</p> <p>24 I think it's reported in here. For the</p>	<p>1 patient will need just one surgery?</p> <p>2 A. No, that's correct, it's not</p> <p>3 clear to me.</p> <p>4 Q. Is it important to you to</p> <p>5 know whether or not a patient you're</p> <p>6 treating for mesh removal is involved in</p> <p>7 litigation?</p> <p>8 A. No, not really.</p> <p>9 Q. Have you evaluated the</p> <p>10 medical literature with regard to</p> <p>11 potential bias by financial gain to</p> <p>12 patients involved in litigation and how</p> <p>13 they report their symptoms to doctors?</p> <p>14 MS. FITZPATRICK: Objection.</p> <p>15 THE WITNESS: No.</p> <p>16 BY MR. SNELL:</p> <p>17 Q. Are you aware if there is</p> <p>18 literature, though, on that topic?</p> <p>19 A. No.</p> <p>20 Q. Haven't you written in the</p> <p>21 past that patients involved in litigation</p> <p>22 have a financial incentive to make</p> <p>23 claims?</p> <p>24 MS. FITZPATRICK: Objection.</p>
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<p>1 sling cohort, less than half had to have</p> <p>2 a second surgery.</p> <p>3 Is that consistent with your</p> <p>4 recollection of this study?</p> <p>5 A. Yes. But the follow-up</p> <p>6 was -- the follow-up for all of these</p> <p>7 things is too short for there to be any</p> <p>8 meaningful conclusion about whether or</p> <p>9 not they needed another operation.</p> <p>10 Q. Well, based on the data,</p> <p>11 though, it was more likely than not that</p> <p>12 one surgery would suffice in this study</p> <p>13 for the sling patients?</p> <p>14 A. I just -- I just said what</p> <p>15 my opinion was.</p> <p>16 Q. In the sling procedure, it</p> <p>17 said 23 percent had more than one</p> <p>18 surgery. So to that -- that, to you,</p> <p>19 does not mean -- 23 percent of the women</p> <p>20 who had these tertiary care center</p> <p>21 treatments had to have more than one</p> <p>22 surgery.</p> <p>23 That does not mean, to you,</p> <p>24 that it's more likely than not that a</p>	<p>1 THE WITNESS: I haven't</p> <p>2 written that, no.</p> <p>3 BY MR. SNELL:</p> <p>4 Q. You haven't?</p> <p>5 In your opinion, does the</p> <p>6 TVT adequately treat stress urinary</p> <p>7 incontinence?</p> <p>8 MS. FITZPATRICK: Objection.</p> <p>9 THE WITNESS: In terms of</p> <p>10 efficacy, yes.</p> <p>11 BY MR. SNELL:</p> <p>12 Q. And in your opinion, I take</p> <p>13 it you believe that the pubovaginal sling</p> <p>14 also adequately treats stress</p> <p>15 incontinence?</p> <p>16 A. Yes.</p> <p>17 Q. Apparently, over lunch, or</p> <p>18 some time, you called someone to try to</p> <p>19 get information about why papers were</p> <p>20 left off of your review?</p> <p>21 A. I did.</p> <p>22 Q. Who did you call?</p> <p>23 A. My previous -- actually, one</p> <p>24 of the authors of the paper, I think it</p>

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<p>1 was Matt Benedon. But he's a previous 2 research coordinator. 3 Q. Where is he at now? 4 A. He's still in New York, but 5 he doesn't work for me anymore. 6 Q. And what did you ask Matt? 7 A. Why those weren't there. 8 Q. What did he say? 9 A. That we used -- if the same 10 author wrote a previous paper using the 11 same cohort of patients, he only included 12 the one with the latest -- our 13 methodology was to only include the one 14 the latest date. 15 So, for example, one of the 16 papers we didn't -- I forget who the 17 first author was, but the senior author 18 was Nilsson, we did not include the 19 five-year paper, we included the 20 seventeen-year paper. There was a series 21 of papers. 22 So there were three that -- 23 that was one. 24 The Serati, or whatever that</p>	<p>1 A. We may -- let me see the 2 paper. 3 MS. FITZPATRICK: This is my 4 copy of it. I don't know what 5 number it is. 6 BY MR. SNELL: 7 Q. You said one with Nilsson. 8 I think that's the one where Nilsson is 9 on. 10 A. Give me one second. 11 Q. Can I look over your 12 shoulder? I can't find mine in that big 13 stack. 14 Yes, this is Nilsson, okay. 15 A. You're correct about that. 16 But that's the explanation. They thought 17 when the computer -- you know, the way we 18 did it, it pulled it up as the same 19 author, and they thought it was the same 20 cohort. 21 Q. But it's clearly not, 22 correct? 23 A. It's clearly not, correct. 24 Q. And it should have been</p>
Page 327	Page 329
<p>1 one was, the 2013 paper was -- the 2 five-year follow-up was published later 3 than the ten-year follow-up, because the 4 ten-year follow-up was just TVT -- 5 Q. Can I stop you right there? 6 A. Yes. 7 Q. First of all, the cohort of 8 patients in Nilsson's study that's been 9 reported out to 17 years, that I know you 10 cited, is not the same cohort of people 11 in the prospective randomized five-year 12 control trial; you and I know that, 13 right? 14 A. They're different -- no, 15 they are different papers, right. 16 Q. They are different cohorts 17 of patients, right? 18 A. Let me see the paper. Which 19 one are you talking about? 20 Q. I'll take these one by one. 21 The first one you mentioned 22 with Nilsson, that's the Laurikainen 23 five-year RCT. 24 Where is your paper at?</p>	<p>1 included, correct? 2 A. Yes, it should have. 3 Q. And Serati, those are two 4 different cohort of patients because the 5 ten-year study was TVT patients and the 6 five-year were TVT-O patients, correct? 7 A. And TVT. One of them had 8 TVT and TOT, I thought. 9 Well, let me see the two 10 papers, and we'll see. 11 MS. FITZPATRICK: I've only 12 got one. I think we only have one 13 marked, and I'm not sure what it 14 is. 15 BY MR. SNELL: 16 Q. Do you have it in front of 17 you there, Doctor? 18 A. I must. 19 MS. FITZPATRICK: Is it 20 Number 12? Here. That's the only 21 one we have. We don't have the 22 second one, I don't think, the 23 2013. 24 THE WITNESS: I need to see</p>

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<p style="text-align: right;">Page 330</p> <p>1 the other one, the one that --</p> <p>2 this is what year? I need to see</p> <p>3 the one that was printed -- what</p> <p>4 year is this?</p> <p>5 This is 2012. We need to</p> <p>6 see the one from 2014. The same</p> <p>7 author had a paper in 2014.</p> <p>8 MS. FITZPATRICK: 2013.</p> <p>9 THE WITNESS: 2013.</p> <p>10 BY MR. SNELL:</p> <p>11 Q. But that was a group of</p> <p>12 TVT-O patients that were only analyzed at</p> <p>13 five years?</p> <p>14 A. Can I just see it?</p> <p>15 Q. I don't have it, but we have</p> <p>16 it on the computer here.</p> <p>17 A. Let me see in the table --</p> <p>18 hold on.</p> <p>19 Let me just see in our</p> <p>20 table. I'll be able to tell just by</p> <p>21 looking in the table.</p> <p>22 Q. I think the simple thing is</p> <p>23 this. I think you should be able to</p> <p>24 agree with me that a ten-year group of</p>	<p style="text-align: right;">Page 332</p> <p>1 on. This doesn't change the</p> <p>2 conclusions one bit.</p> <p>3 BY MR. SNELL:</p> <p>4 Q. I thought you said that</p> <p>5 there is less long-term ten-year data on</p> <p>6 TVT?</p> <p>7 A. Including this. I already</p> <p>8 went through the fact that the</p> <p>9 methodology to look at the kinds of</p> <p>10 complications that we saw is not</p> <p>11 sufficient. It didn't seek it out.</p> <p>12 I mean, it didn't have a</p> <p>13 way -- I mean, again, I agree that 8</p> <p>14 percent is a great loss to follow up.</p> <p>15 But the problem is, it's not so great --</p> <p>16 it's great for efficacy. But it's not so</p> <p>17 great looking for complication that</p> <p>18 occurs in 1 or 2 percent of patients.</p> <p>19 So if only one -- there's</p> <p>20 only one patient, one or two patients</p> <p>21 that had that complication, they were</p> <p>22 more likely to be in the</p> <p>23 loss-to-follow-up group according to --</p> <p>24 or -- they were very likely to be, I</p>
<p style="text-align: right;">Page 331</p> <p>1 women who got TVT implanted is not the</p> <p>2 same group who had five-year follow-up</p> <p>3 after a TVT-O implanted?</p> <p>4 A. Of course. But --</p> <p>5 Q. In your paper, you cited to</p> <p>6 this five-year TVT-O paper, and I'll give</p> <p>7 you that, it's in there, but the ten-year</p> <p>8 TVT group was not in there?</p> <p>9 A. Just let me check one thing.</p> <p>10 That's correct. And that</p> <p>11 was -- that was just an error. But the</p> <p>12 error was because it was the same author</p> <p>13 with mesh slings. And our methodology</p> <p>14 said that if it was -- they mistakenly</p> <p>15 thought it was the same cohort.</p> <p>16 Q. Clearly, it's important to</p> <p>17 capture ten-year TVT studies that are out</p> <p>18 there in the published literature and</p> <p>19 journals like European Urology, correct?</p> <p>20 MS. FITZPATRICK: Objection.</p> <p>21 THE WITNESS: Not to -- not</p> <p>22 in a safety consideration for</p> <p>23 synthetic sling study that is</p> <p>24 already -- there's plenty of data</p>	<p style="text-align: right;">Page 333</p> <p>1 couldn't say that they were more likely</p> <p>2 to be.</p> <p>3 They are at least one-third</p> <p>4 more likely to be in that group because</p> <p>5 we know at least one-third of the</p> <p>6 patients don't go back to their original</p> <p>7 doctors.</p> <p>8 So that an 8 percent loss to</p> <p>9 follow up, although extraordinarily</p> <p>10 commendable for an efficacy study, is not</p> <p>11 so commendable to look for something that</p> <p>12 happens 1 or 2 percent of the time.</p> <p>13 Q. The problem with what you</p> <p>14 just said, though, Doctor, is when you</p> <p>15 said we know a third of the patients</p> <p>16 don't go back to their doctors, we know</p> <p>17 that in Serati, 92 percent of them went</p> <p>18 back to their doctors, right?</p> <p>19 MS. FITZPATRICK: Objection.</p> <p>20 THE WITNESS: That's right.</p> <p>21 But 8 percent did not.</p> <p>22 BY MR. SNELL:</p> <p>23 Q. But 8 percent and a third is</p> <p>24 a big difference, isn't it?</p>

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<p style="text-align: right;">Page 334</p> <p>1 MS. FITZPATRICK: Objection.</p> <p>2 THE WITNESS: Well, no, no.</p> <p>3 I actually stand by what I said.</p> <p>4 I don't think I need to say it</p> <p>5 again.</p> <p>6 BY MR. SNELL:</p> <p>7 Q. So in Serati's paper, where</p> <p>8 only 8 percent didn't go back to the</p> <p>9 doctor, why are you telling me that we</p> <p>10 know a third of patients don't go back to</p> <p>11 their doctor?</p> <p>12 MS. FITZPATRICK: Objection.</p> <p>13 Mischaracterizes his testimony.</p> <p>14 THE WITNESS: The reason I</p> <p>15 said that is there's a chance that</p> <p>16 the -- let's say these -- I forget</p> <p>17 the numbers now, but these were,</p> <p>18 like, 60 patients or 70 patients.</p> <p>19 So 60 patients, if one -- we</p> <p>20 would not expect there to be more</p> <p>21 than one, say, erosion out of</p> <p>22 that. That would be -- you know,</p> <p>23 that would, or urethral</p> <p>24 obstruction that required -- say</p>	<p style="text-align: right;">Page 336</p> <p>1 BY MR. SNELL:</p> <p>2 Q. I'm really trying to</p> <p>3 understand your methodology and your</p> <p>4 statement there.</p> <p>5 MS. FITZPATRICK: Objection</p> <p>6 to the form of the question.</p> <p>7 THE WITNESS: I'll try to</p> <p>8 say it again.</p> <p>9 I didn't say they're more</p> <p>10 likely to be in that group. I</p> <p>11 didn't say that they are more</p> <p>12 likely to be in that group. It's</p> <p>13 just that I think that -- maybe I</p> <p>14 did say that. If I did, I</p> <p>15 misspoke.</p> <p>16 I said there's a chance that</p> <p>17 they could be in the group. And</p> <p>18 since the complications we're</p> <p>19 talking about are so uncommon,</p> <p>20 okay, I don't think it's fair to</p> <p>21 say that if a complication didn't</p> <p>22 occur in the 92 percent of the</p> <p>23 patients that were followed up,</p> <p>24 that, therefore, it never</p>
<p style="text-align: right;">Page 335</p> <p>1 requiring surgery would be 1 or 2</p> <p>2 percent. Okay.</p> <p>3 So there only -- in that 8</p> <p>4 percent, the one patient could</p> <p>5 have been the one patient who had</p> <p>6 the complication, and that one</p> <p>7 patient, it would be more likely</p> <p>8 that that person would be in the</p> <p>9 loss-to-follow-up group than in</p> <p>10 the not loss-to-follow-up group.</p> <p>11 BY MR. SNELL:</p> <p>12 Q. How is it that you can say</p> <p>13 that that one patient is more likely in</p> <p>14 the loss-to-follow-up group than the 92</p> <p>15 percent of the patients who did return?</p> <p>16 MS. FITZPATRICK: Objection.</p> <p>17 THE WITNESS: I already</p> <p>18 explained my rationale for that.</p> <p>19 BY MR. SNELL:</p> <p>20 Q. I don't understand it.</p> <p>21 It would seem to me that</p> <p>22 sheer statistical 92 percent probability</p> <p>23 that they would come back?</p> <p>24 MS. FITZPATRICK: Objection.</p>	<p style="text-align: right;">Page 337</p> <p>1 occurred. That's all I'm saying.</p> <p>2 BY MR. SNELL:</p> <p>3 Q. Okay. We can agree that in</p> <p>4 Serati's paper, where 92 percent of the</p> <p>5 patients did come back and they didn't</p> <p>6 report any de novo dyspareunia and they</p> <p>7 did not see any exposure, that's actually</p> <p>8 a good thing for those patients who came</p> <p>9 back and were able to be evaluated?</p> <p>10 A. I'm going to split it</p> <p>11 between the dyspareunia and the erosion.</p> <p>12 All the patients were</p> <p>13 examined, so I'll give you that.</p> <p>14 But the dyspareunia, if you</p> <p>15 don't ask about it and you don't know if</p> <p>16 the patient is sexually active, you can't</p> <p>17 make a comment about dyspareunia, in my</p> <p>18 judgment. If they say they have</p> <p>19 dyspareunia, you can make a comment. If</p> <p>20 you did not say specifically, do you have</p> <p>21 sex and does it hurt, I don't think you</p> <p>22 can say -- you can make a comment.</p> <p>23 Q. But when the authors report</p> <p>24 there was no de novo dyspareunia, that</p>

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<p style="text-align: right;">Page 338</p> <p>1 means they asked about it, they assessed 2 it, right? 3 A. If that were the case, it 4 would be in the methods. And if it 5 wasn't -- if they asked about it and did 6 not put it in the methods, then it's 7 their fault for not putting it in the 8 methods. And if they didn't ask about 9 it, then they can't conclude it. 10 And I don't even like 11 talking about this because I think it's 12 very good paper. I don't mean to malign 13 the authors at all. This is an excellent 14 paper, but just not with respect -- they 15 did the best they could with this stuff. 16 But it's not good enough to satisfy me 17 that if the patients don't complain of 18 pain, they don't have it. 19 I haven't -- I made my 20 statement. 21 Q. Regardless, that's a paper 22 that should have been in your review, 23 right? 24 A. Yes.</p>	<p style="text-align: right;">Page 340</p> <p>1 data and we did use it for calculations. 2 It just didn't make -- it just didn't get 3 in that table. 4 Q. So there is much more five 5 year long-term data in the literature 6 than what you put in that table, correct? 7 A. Well, there are three. 8 Q. Three that I showed you 9 today? 10 A. Yes. 11 Q. There could be 12 more? 12 MS. FITZPATRICK: Objection. 13 THE WITNESS: I don't know. 14 But if there are, let's not 15 discuss them today. 16 BY MR. SNELL: 17 Q. Is part of your methodology 18 based on case series? 19 A. Yes. 20 Q. Do you give more weight to 21 case series than randomized control 22 trials or systematic reviews? 23 A. I give weight to anything 24 that documents a complication. I don't</p>
<p style="text-align: right;">Page 339</p> <p>1 Q. And you were about to -- 2 were you about to give me some 3 justification for why the other paper 4 didn't show up in there? 5 A. Which one was that? 6 Q. Heinonen, 10.5 years, 7 follow-up, no long -- 8 A. Which one? 9 Q. Heinonen, 10.5 years -- 10 A. I need to see it. 11 MS. FITZPATRICK: This one. 12 BY MR. SNELL: 13 Q. No late tissue reaction 14 exposure, where they did vaginal 15 examinations with speculum? 16 A. This just missed the table, 17 it's in the paper. This is referenced, 18 it's part of our data. We just -- it 19 didn't get in the table. 20 Q. In your paper, you reported 21 there were only 11. 22 That one obviously should 23 have been in there as well? 24 A. Yeah. But we did use it as</p>	<p style="text-align: right;">Page 341</p> <p>1 give weight to someone that doesn't 2 comment on -- you know, on complications. 3 So most of the studies, 4 many -- I would say -- I could say that 5 most of the studies don't even have 6 anything in their methodology to accrue 7 complications, other than -- than patient 8 reported. 9 So if the patient says -- 10 said that it hurt, something hurts, they 11 would accept it. But they don't -- if 12 they don't prompt for it, they don't 13 check for it, I don't give that any 14 credence at all. 15 Q. Nilsson, 17-year paper? 16 A. Yes. 17 Q. Are you critical of the loss 18 to follow up in that paper as being 19 something outside the norm for a 17-year 20 data set or is that within the norm of 21 what you would expect at 17 years? 22 A. Again, the loss to follow 23 up, I think, was acceptable for that 24 period of time. But some of the stuff</p>

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1 IN THE UNITED STATES DISTRICT COURT
 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
 2 AT CHARLESTON

3 IN RE: ETHICON, INC., :Master File No.
 4 PELVIC REPAIR SYSTEM :2:12-MD-0237
 PRODUCTS LIABILITY :
 5 LITIGATION :MDL No. 2327

6 THIS DOCUMENT RELATES TO :JOSEPH R. GOODWIN
 THE CASES LISTED BELOW :U.S. DISTRICT JUDGE
 7 -----

8	Mullins, et al. V.	2:12-cv-02952
9	Ethicon, Inc., et al.	
10	Sprout, et al. V.	2:12-cv-07924
11	Ethicon, Inc., et al.	
12	Iquinto v. Ethicon,	2:12-cv-09765
13	Inc., et al.	
14	Daniel, et al. V.	2:13-cv-02565
15	Ethicon, Inc., et al.	
16	Dillon, et al. V.	2:13-cv-02919
17	Ethicon, Inc., et al.	
18	Webb, et al. V.	2:13-cv-04517
19	Ethicon, Inc., et al.	
20	Martinez v. Ethicon,	2:13-cv-04730
21	Inc., et al.	
22	McIntyre, et al. V.	2:13-cv-07283
23	Ethicon, Inc., et al.	
24	Oxley v. Ethicon,	2:13-cv-10150
	Inc., et al.	
	Atkins, et al. V.	2:13-cv-11022
	Ethicon, Inc., et al.	
	Garcia v. Ethicon,	2:13-cv-14355
	Inc., et al.	
	Lowe v. Ethicon,	2:13-cv-14718
	Inc., et al.	
	Dameron, et al. V.	2:13-cv-14799
	Ethicon, Inc., et al.	
	Vanbuskirk, et al. V.	2:13-cv-16183
	Ethicon, Inc., et al.	

22
 23

 SEPTEMBER 24, 2015
 24 CONTINUED DEPOSITION OF JERRY G. BLAIVAS, M.D.

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1	CAPTION CONTINUED:	
2	Mullens, et al. V.	2:13-cv-16564
3	Ethicon, Inc., et al.	
	Shears, et al. V.	2:13-cv-17012
4	Ethicon, Inc., et al.	
	Javins, et al. V.	2:13-cv-18479
5	Ethicon, Inc., et al.	
	Barr, et al. V.	2:13-cv-22606
6	Ethicon, Inc., et al.	
	Lambert v. Ethicon,	2:13-cv-24393
7	Inc., et al.	
	Cook v. Ethicon, Inc.	2:13-cv-29260
8	Stevens v. Ethicon,	2:13-cv-29918
	Inc., et al.	
9	Harmon v. Ethicon, Inc.	2:13-cv-31818
	Snodgrass v. Ethicon,	2:13-cv-31881
10	Inc., et al.	
	Miller v. Ethicon, Inc.	2:13-cv-32627
11	Matney, et al. V.	2:14-cv-09195
	Ethicon, Inc., et al.	
12	Jones, et al. V.	2:14-cv-09517
	Ethicon, Inc., et al.	
13	Humbert v. Ethicon,	2:14-cv-10640
	Inc., et al.	
14	Gillum, et al. V.	2:14-cv-12756
	Ethicon, Inc., et al.	
15	Whisner, et al. V.	2:14-cv-13023
	Ethicon, Inc., et al.	
16	Tomblin v. Ethicon,	2:14-cv-14664
	Inc., et al.	
17	Schepleng v. Ethicon,	2:14-cv-16061
	Inc., et al.	
18	Tyler, et al. V.	2:14-cv-19110
	Ethicon, Inc., et al.	
19	Kelly, et al. V.	2:14-cv-22079
	Ethicon, Inc., et al.	
20	Lundell v. Ethicon,	2:14-cv-24911
	Inc., et al.	
21	Cheshire, et al. V.	2:14-cv-24999
	Ethicon, Inc., et al.	
22	Burgoyne, et al., V.	2:14-cv-28620
	Ethicon, Inc., et al.	
23	Bennett, et al., V.	2:14-cv-29624
24	Ethicon, Inc., et al.	

Jerry G. Blaivas, M.D.

1 Continued transcript of JERRY G. BLAIVAS,
2 M.D., called for Oral Examination in the
3 above-captioned matter, said deposition taken by and
4 before SILVIA P. WAGE, a Certified Shorthand
5 Reporter, Certified Realtime Reporter, Registered
6 Professional Reporter, and Notary Public for the
7 States of New Jersey, New York, Pennsylvania and
8 Delaware, at the offices of URO CENTER, 445 East
9 77th Street, New York, New York, on Thursday,
10 September 24, 2015, commencing at 2:48 p.m.

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Jerry G. Blaivas, M.D.

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1 Q. I would not misrepresent some data to
2 you.
3 A. No.
4 Q. Is that okay?
5 A. Yeah, I agree.
6 Q. A P-value of less than .03 is
7 statistically significant, correct?
8 A. Yes.
9 Q. Okay. And there was a significant
10 decline in subjective cure that was seen in the IVS
11 cohort, correct?
12 A. Correct.
13 Q. Vaginal erosions were tracked in the
14 study as well, right?
15 A. Yes. Well, it -- it wasn't tracked.
16 It says that it was defined as -- it doesn't
17 actually say how they determined that.
18 Q. You see they say that vaginal
19 erosions were found in 11.8 percent of women in the
20 IVS group and none in the TVT group, correct?
21 A. Yes.
22 Q. And under the results follow-up,
23 you'll see the median follow-up in this study was
24 78 months, correct?

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1 A. Let me just see. I just want to
2 check one thing out.
3 Yeah, I'm not finding the numbers lost to
4 follow-up.
5 MR. SNELL: [MOTION] Move to strike.
6 Q. You see my question was, Doctor --
7 and I have very limited time -- the median length of
8 follow-up in the TVT group was 78 months, correct?
9 A. Yes.
10 Q. Alright. And you'll see, actually,
11 all of Page 706, they have a whole section on the
12 treatment of these vaginal erosions.
13 A. Yes.
14 Q. And that flows all the way over to
15 the next page, Table 5, where they identify all the
16 different presenting symptoms in women with vaginal
17 erosions, correct?
18 A. Yes.
19 Q. Including how treatment was necessary
20 or not in the women who had the vaginal erosions,
21 correct?
22 A. Yes.
23 Q. And, just to reiterate, and all of
24 these patients with erosions were in the IVS group,

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1 correct?
2 A. Yes.
3 Q. And the IVS mesh is not a Type 1
4 macroporous monofilament polypropylene mesh,
5 correct?
6 A. The which?
7 Q. The IVS mesh is not a Type 1
8 monofilament --
9 A. No, it's not.
10 (There is a discussion off the record.)
11 A. Excuse me. It's not. It's not.
12 Q. Just so we have a clear record now,
13 the IVS where there was over an 11 percent rate of
14 vaginal exposure seen is not a Type 1 macroporous
15 monofilament polypropylene mesh like TVT retropubic,
16 correct?
17 A. Correct.
18 Q. Alright. And do you have any idea
19 why this paper wasn't cited in your review?
20 MS. FITZPATRICK: Objection.
21 A. I assume it was likely an exclusion
22 criteria based on our very detailed methodology. I
23 don't know.
24 Q. You don't know that as you sit here

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1 today?
2 A. No.
3 (Deposition Exhibit Blaivas 26, Long-term
4 Results of the Tension-free Vaginal Tape Procedure
5 in an Unselected Group: A 7-year Follow-up Study
6 authored by Andreas Reich, Frauke Kohorst, Rolf
7 Krelenberg and Felix Flock, was marked for
8 identification.)
9 Q. Exhibit 26, you see this is long-term
10 results of the TVT procedure in an unselected group
11 of patients, seven-year follow-up, correct?
12 A. Let me look at it. I mean, I'm
13 seeing this for the first time.
14 Q. Fair enough. Let me ask you this.
15 This is, actually, published in the Journal
16 of Urology, correct?
17 A. Yes.
18 Q. That's a journal you get, right?
19 A. Yes, I get it.
20 Q. Is that the journal to my left here
21 on the bookcase?
22 A. It is.
23 Q. Okay. Fair enough.
24 MR. SNELL: Go off the record.